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CEPERLEY, MARY

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 18

Date mailed : 7/30/02

Application Number: 09/368,010
Filing Date: August 03, 1999
Appellant(s): WILLIAMS ET AL.

Michael B. Farber
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03 May 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. There are no such appeals or interferences pending.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The statement regarding the amendments after final is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 11, 12, 31-33, 50, 51, and 61, all of the claims on appeal, are to be considered together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following rejections are applicable to the appealed claims:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as ***to enable any person skilled in the art*** to which it pertains, or with which it is most nearly connected, ***to make*** and use ***the same*** and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 12, 31-33, 50, 51, and 61 stand rejected under 35 USC 112, first paragraph, as being based on a specification which fails to provide an adequate enabling written description for one of ordinary skill in the art of how to ***reproducibly*** make the claimed monoclonal antibodies which have very specific characteristics ***without undue experimentation***. See paragraph 2. of the final rejection of 05 November 2001.

(11) Response to Argument

Prosecution History

Original claim 11 was a product-by-process claim directed to a monoclonal antibody produced from an immunogenic conjugate in which the tacrolimus hapten was coupled to an immunogenic carrier through a C22-carboxymethyl oxime linkage. As a product-by-process claim, claim 11 was rejected under 35 USC 102/103, in accordance with MPEP 2113, as being anticipated by or obvious over prior art which described monoclonal antibodies having specificity for tacrolimus (see paragraph 6. of the 07 March 2001 Office action). ***At the time of the first Office action on the merits, no rejection of claim 11 (nor any of claims 12, 31-33, 50, 51, and 61) was made under 35 USC 112, first paragraph.*** There was no question of enablement for these claims as originally filed, i.e. one of ordinary skill in the art, using the description provided in the instant specification, would have no problem preparing the C22 immunogenic conjugate of claim 11 and using it to obtain "a monoclonal antibody to tacrolimus ". No undue experimentation would be involved in the preparation of such an antibody.

However, appellant's 13 August 2001 response to the 35 USC 102/103 rejection was to amend claim 11 to include ***very specific limitations on the specificity of the monoclonal antibody***, namely, that the monoclonal antibody

"...has a binding affinity for tacrolimus of about 3.7×10^9 liters/mole, that cross-reacts with 13-demethyl tacrolimus, and that has less than about 8% cross-reactivity to all of the following tacrolimus metabolites: 15-demethyl tacrolimus; 31-demethyl tacrolimus; 13,31-didemethyl tacrolimus; 15,31-didemethyl tacrolimus; and 12-hydroxy tacrolimus."

It is the examiner's position that the claims, ***as amended***, are based on a specification which does not enable a person skilled in the art to ***reproducibly obtain even a single monoclonal***

antibody having the required characteristics as recited in amended claim 11. The claimed monoclonal antibody requires, at a minimum, ***six very specific binding affinity and cross-reactivity characteristics.*** Given the state of the art, it would be unreasonable to assume that one skilled in the art could obtain even a single monoclonal antibody meeting the specifications of claim 11 if he prepared and used the immunogenic conjugate described in the working example and screened a very large number of hybridomas.

The state of the art as it relates to the production and screening of monoclonal antibodies and the Wands' factors

The examiner agrees with appellant's assessment of the state of the art as it appears in the last paragraph of page 8 of the appeal brief. Namely, that "a certain amount of routine experimentation associated with the optimization of the Kohler-Milstein monoclonal antibody production process does not constitute undue experimentation". However, the examiner does not agree with the appellant's assessment of the instant fact situation as it relates to the factors considered by the court in *In re Wands*, 858 F2d 731, as described by appellant's at pages 11-15 of the appeal brief.

The quantity of experimentation involved in obtaining a monoclonal antibody having the required specificity of claim 11 can be likened to screening a large human population to find a single person having six specific characteristics, for example, screening for a person who has **all** of the following characteristics: ***a)*** a certain index of refraction of the iris of the eye, ***b)*** a specific subset of fingerprint characteristics, ***c)*** a certain hair color, ***d)*** a certain age within days, ***e)*** a certain ethnicity, and ***f)*** certain specific genes. The likelihood of finding such a person would clearly require an undue amount of screening and it is unclear that even with extensive screening one would ever be able to find such an individual. The state of the art with regard to monoclonal antibody production is similar in that it involves a strictly trial and error process of screening large numbers of hybridomas for those producing antibodies having the requisite characteristics. Such a screening of large numbers of hybridomas is

considered to be routine in the art as long as there is ***a reasonable expectation*** that a monoclonal antibody having the required characteristics can be found. As stated in the section entitled *Prosecution History* above, the screening needed to obtain monoclonal antibodies having the characteristics as originally claimed in claim 11 (having very general specificity) would be well within the level of skill in the art. With regard to ***the claims as amended***, however, the ***appellant is in possession of the one and only monoclonal antibody having the specificity recited in claim 11*** and there is no reasonable guarantee or expectation that any other person skilled in the art, following appellant's working example, would be able to obtain this particular antibody or any other which has the required characteristics. (See the analogy to the screening of a human population above.) The only way in which the public access to a monoclonal antibody having the characteristics of claim 11 can be guaranteed is through the deposit of the hybridoma which produces the monoclonal antibody designated as 1H6 (specification, page 30, line 28) to an acceptable depository in accordance with the procedures set forth in MPEP 2402-2405. The fact that appellant has provided a description and working example of how ***he*** obtained a single monoclonal antibody having the recited characteristics does not in any way guarantee that ***another*** skilled in the art could obtain such an antibody. The *quid pro quo* of obtaining a patent is giving the public access to one's invention in return for certain intellectual property rights reserved to applicant. Without such a deposit, applicant has not made the antibody of claim 11 accessible to the public.

For the above reasons, it is believed that the rejection of record should be sustained.

(12) Allowable Subject Matter

Upon appropriate deposit of the monoclonal antibody designated as 1H6 in an acceptable depository under the conditions of the Budapest Treaty, a claim directed to this specific monoclonal antibody would be allowable.

Respectfully submitted,

Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641

July 25, 2002

Conferees

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